Protocol Title: VRC 325: A Phase I Open-Label Clinical Trial to Evaluate the Dose, Safety, Tolerability and Immunogenicity of Mosaic Quadrivalent Influenza Vaccine Compared with a Licensed Inactivated Seasonal QIV, In Healthy Adults

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PRINCIPAL INVESTIGATOR: Alicia Widge, MD, MS

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STUDY SITE: NIH / NIAID / VRC / Vaccine Evaluation Clinic (VEC)

Cohort: *Healthy volunteer*

Consent Version: May 14, 2021 (Version 1.0)

WHO DO YOU CONTACT ABOUT THIS STUDY?

Principal Investigator: Alicia Widge, MD, MS; [redacted]

Study Coordinator: Floreliz Mendoza, RN; [redacted]

KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at the NIH is your choice.

This is a study of an experimental vaccine called the FluMos-v1 vaccine for prevention of the seasonal influenza (flu). The main purpose of this study is to see if the experimental vaccine is safe and how your body responds to it. Since this is the first time that the FluMos-v1 vaccine will be given to people, we do not know how your body will respond. We also want to study immune responses to this vaccine compared to the 2020-2021 FDA-approved seasonal flu vaccine, Flucelvax®. This study is not designed to protect you from the flu.

About 35 people will take part in this study at the NIH Clinical Center in Bethesda, MD. You will be in the study for about 40 weeks (10 months) and get either FluMos-v1 or Flucelvax vaccination depending on what group you are in. You will have about 10 clinic visits over 40 weeks. In addition, 6-16 tubes of blood will be drawn at many of these visits. You will be compensated for your time and efforts for taking part in this study.

You will get the experimental FluMos-v1 vaccine or Flucelvax by injections (shots) in the upper arm muscle. This is called an intramuscular "IM" injection. We will use a needle and syringe to give you the FluMos-v1 or Flucelvax vaccines.

You could have side effects from the FluMos-v1 or Flucelvax vaccines, such as fever, tiredness, body aches, headache, chills, nausea, and joint pain. These side effects can also occur with FDA-approved flu vaccines. The side effects usually occur within the first 24 hours after the vaccine

is given. Rarely, side effects of trouble breathing, itchiness, rash, hives, swelling, or chest pain may occur. Some vaccines have a risk of serious allergic reactions that can be life threatening.

We do not know how the experimental vaccines may affect a fetus or nursing infant. Therefore, women who can become pregnant must have a negative pregnancy test before the vaccine injection and agree to use effective birth control beginning at least 21 days before the injection until the end of the study

During the study, we will collect blood samples from you. Some of your blood will be stored for future research.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research interventions in which they would want to participate. Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

Influenza (flu) is a contagious respiratory illness caused by influenza viruses that infect the nose, throat, and sometimes the lungs. It can cause mild to severe illness. Serious outcomes of flu infection can result in hospitalization or death. Some people, such as older people, young children, and people with certain health conditions, are at high risk of serious flu complications.

This is the first study in people of this experimental vaccine for prevention of the seasonal flu. "Experimental" means that the study vaccine has not been approved by the Food and Drug Administration (FDA). The FDA allows this vaccine to be used for research purposes only.

Vaccines are given to teach the body to prevent or fight an infection. In this study, we are testing one experimental vaccine that was developed by the Vaccine Research Center (VRC) at the NIH: FluMos-v1 vaccine, VRC-FLUMOS0111-00-VP. In this consent form, the study vaccine will be called the "FluMos-v1 vaccine." This vaccine is intended to help the body to make an immune response to the seasonal flu.

Most vaccines are made of proteins that are injected into a muscle. Proteins are natural substances that the body uses as building blocks. This vaccine is made in the laboratory with five proteins: four proteins similar to the seasonal influenza and one protein called lumazine synthase, which helps make vitamin B2 in the yeast *Candida albicans (C. albicans*). These five proteins have been

modified in the laboratory. When combined, they make a particle that looks like the outside of the seasonal flu viruses. The body's immune system may respond to this particle.

This is the first study to give the FluMos-v1 vaccine to humans. We do not know if the FluMos-v1 vaccine will protect you from flu. There is no virus or yeast in the vaccine, so you cannot get an influenza or *C. albicans* infection from this vaccine.

The purpose of this research study is to see if the FluMos-v1 vaccine is safe and how your body responds to it. We will tell you if we learn anything new during this study that might cause you to change your mind about staying in the study. At the end of the study, we will tell you when study results may be available and how to learn about them.

WHAT WILL HAPPEN DURING THE STUDY?

There will be two different vaccines given in this study. The experimental FluMos-v1 vaccine will be given at 20 micrograms (mcg) and 60 mcg. The FDA-approved Flucelvax vaccine will be given at the standard dose of 60 mcg.

The table below shows the study plan:

Group	Age Cohort	Subjects	Day 0	Product
1A 1B*	18-50	**5**	20 micrograms	FluMos-v1
2A 2B*	18-50	**15**	60 micrograms	FluMos-v1
3A 3B*	18-50	**15**	60 micrograms	Flucelvax®
Total		**35**	*Includes people who received the 2020-2021 seasonal influenza vaccine.	

Under current COVID-19 precautions, all subjects will be tested for COVID-19 up to 4 days before vaccination, even if you have been vaccinated for COVID-19. You are required to come to the clinic so we can take mucosal samples from your nose. The test must show that you are negative for COVID-19 infection before you can get the vaccine. In time, this COVID-19 testing may not be required. We will update you if conditions change and it is no longer needed.

If you are a woman who can get pregnant, we will do a pregnancy test before your vaccination. The test must show that you are not pregnant before you can get the vaccine.

Follow-Up after FluMos-v1 Vaccine Administration

You will need to stay in the clinic for at least 30 minutes after vaccination. If you are unwell or have ongoing symptoms, you will be asked to stay in the clinic until evaluation and discharge by a study clinician. This includes the possibility of an overnight inpatient stay to evaluate for safety.

In keeping with the NIH CC policy and good medical practice, acute medical care will be provided to subjects for any immediate allergic reactions or other injury resulting from participation in this research study.

The day after your vaccination, clinic staff will call to check on you. Also, after your vaccination, you will need to complete a diary card for 7 days. On the diary card you will need to record any symptoms that you may have for data analysis and not because of any risk of getting the flu from this vaccine. We will give you a thermometer to check your temperature every day for 7 days, even if you feel well. We will also give you a ruler to measure any skin changes at the injection site. You will get a password to a secure website where you can enter this data online. If you do not have access to the internet, you can use a paper diary card instead.

If you have any symptoms or feel unwell, you should tell a clinic nurse or doctor as soon as possible. You can reach the staff by phone 24 hours a day. If you have symptoms, you may be asked to come to the clinic for a checkup. It is very important that you follow the instructions from the clinic staff.

Follow-up visits allow us to check you for any health changes or problems. We will ask you how you are feeling and if you have taken any medications. We will take about 6-16 tubes of blood at each visit for safety and/or research tests. Blood draw volumes will be within NIH Clinical Center limits. We will tell you right away if any of the clinical laboratory test results show a health problem. You might need to have extra clinic visits or laboratory tests if you have health changes that need to be checked.

Clinical studies follow a set schedule. **It is important that you follow the schedule as closely as possible**. **You should try to not miss any visits.** You should contact the clinic staff as soon as possible if you need to change the date or time of any study visit.

Collection of Blood: We will draw your blood before your vaccination and at each scheduled follow-up clinic visit. Some of the blood that we take will be used for research and some will be used so we can monitor your health throughout the study.

For all subjects we will collect 6 to 16 tubes or 4 to 10 tablespoons of blood from you at each study visit. The total amount of blood drawn from you during the entire 40 week study will be about 958 mL. However, we will not draw more than 550 mL in any 8 week period as per NIH Clinical Center guidelines.

Collection of Nose and Throat Secretions for Diagnosis: If you are not feeling well and have any of the following symptoms at any time during the study, it is very important for you to contact the clinic. You may have a flu-like illness or the flu. Symptoms include:

- fever of 100^0 F or higher,
- runny nose,
- sore throat,
- headache,
- feeling more tired than usual
- muscle aches.

If you have any of these symptoms, you will need to come to the clinic so that we can swab your nose and throat to test for the flu and other common causes. We will use a thin disposable swab to for this test.

Collection of Oral (mouth) Mucosal Samples for Research: We will collect oral mucosal samples from all groups at Visit 02, Visit 04, Visit 05, and Visit 07. For us to get the best sample, it is best that you do not eat, drink, or smoke for 1 to 2 hours before this procedure. The purpose of collecting these samples is to study the mucosa immune response. We will use a thin disposable swab to collect this sample. We will give you a schedule so you know when this sample collection will be done.

Apheresis: If you are in Groups 2A-2B and 3A-3B, we would like to collect your blood one time by a method called "apheresis" at 2 weeks after your study injection. This procedure is optional and choosing not to take part will not affect your study participation.

To be eligible for apheresis, you must not:

- have an unstable heart as indicated by your medical history and test results
- have blood pressure greater than 180/100
- have a known blood clotting disorder
- be pregnant or breast feeding
- have a condition that the attending physician or the apheresis clinic staff considers a reason to not do an apheresis procedure.

Before apheresis, we will check your weight, pulse and blood pressure. We will ask questions about your general health and medical history. If you are a woman who can get pregnant, we will do a pregnancy test before the apheresis procedure. The test must show that you are not pregnant. The apheresis staff will prick your finger to test your blood for anemia before the procedure.

During the procedure, you will lay on a recliner, couch, or hospital bed. A sterile needle will be placed into a vein in both of your arms. The kits used to collect apheresis samples are sterile, single-use, disposable sets that are not in contact with any person's bodily fluids other than yours. No blood products are given to you during these procedures. Apheresis is done at the NIH Clinical Center, and a physician from the NIH Department of Transfusion Medicine will be available in or near the apheresis area at all times.

In the apheresis procedure, blood is removed through a needle in the vein of one arm, spun in a machine that separates the white blood cells and then the rest of your blood is returned to you through a needle in the other arm. A medication called Citrate, is added to the blood while in the machine to prevent your blood from clotting.

The purpose of this procedure is to allow us to get a large number of white blood cells that cannot be collected by simple blood drawing. We want to study these white blood cells. The number of white blood cells collected is a small fraction of the total amount in your body. The body quickly replaces the cells that have been removed. The NIH Blood Bank at the Clinical Center and other blood banks use similar procedures every day to collect blood samples from donors. We will not use your samples for transfusion or therapy. The procedure will take approximately 3-4 hours.

MONITORING OF THE STUDY

This study will be monitored by a group of physicians and scientists at NIH. This group will review the study information and will pay close attention to any reactions. If there are serious side effects, study injections may be delayed or canceled.

GENETIC TESTING

Some of the blood drawn from you during this study will be used for genetic tests. Some genetic tests are done in research studies to see if there are genetic difference in immune responses. Your blood sample used in these genetic tests will not have your name on it, and the results will not be in your medical record.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in the study:

You will have 1 vaccination visit, 1 phone call follow-up, and 8 follow-up clinic visits over 40 weeks.

The vaccination visit will take about 6 hours. Most other follow-up clinic visits will take about 1 to 2 hours; the optional apheresis visit will take 3 to 4 hours.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to enroll 35 people. This includes 5 people who will get the 20 mcg dose of FluMos-v1 vaccine, 15 people who will get the 60 mcg dose of FluMos-v1, and 15 people who will get the standard 60 mcg dose of Flucelvax.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

Possible Risks of the FluMos-v1 Vaccine

The FluMos-v1 vaccine has not been given to people before. It may have unknown risks. It has been tested in mice and rabbits. The vaccine did not cause any unusual side effects and met the safety criteria to be tested in humans. You may experience any of the following: arm discomfort, redness of the skin or mild bruising at the injection site. Also, fever, chills, rash, aches and pains, nausea, headache, dizziness, and feeling tired and/or unwell.

Possible Risks of the Flucelvax Vaccine

You may experience any of the following: arm discomfort, redness of the skin or mild bruising at the injection site. Also, fever, chills, rash, aches and pains, nausea, headache, dizziness, and feeling tired and/or unwell. These types of reactions are usually most common within the first 24 hours after vaccination and typically last 1 to 3 days. Over-the-counter medicine, like acetaminophen (Tylenol) or ibuprofen, may be used to help these symptoms.

Very rarely, a serious allergic reaction with symptoms like hives, trouble breathing, or sudden weakness may occur shortly after any vaccination. This is called "anaphylaxis" and may be life-threatening. While you are waiting in the clinic after the vaccination, we will monitor you for anaphylaxis. Treatment for anaphylaxis will be given right away if it occurs.

Possible Risks of Injections

Temporary stinging, pain, redness, soreness, itchiness, swelling, or bruising may occur at the site of the injection.

Possible Risks of Blood Drawing

Blood drawing may cause pain, bruising, and lightheadedness or fainting. Rarely, an infection at the site where the blood is taken may happen.

Possible Risks of Mucosal Sample Collection

Samples collected by rubbing swabs over mucosal surfaces in the mouth, nose, or throat can cause brief discomfort or a little bleeding.

Possible Risks of Apheresis

Apheresis is generally safe, and side effects are rare. Pain, bruising or discomfort at the needle placement site may occur. Sometimes apheresis causes a tingling sensation around the lips, nose and mouth, coolness all over, and/or slight nausea. This can usually be relieved by slowing or temporarily stopping the apheresis or taking an antacid with calcium pill, like Tums®. Other possible side effects are anxiety, vomiting, and lightheadedness. Temporary lowering of the blood pressure may develop. There is the rare possibility of infection, fainting, or seizure. Very rarely a nerve problem at the needle placement site may occur. Also, very rarely, a machine malfunction may occur and result in the loss of about one unit (one pint) of blood.

There are theoretical risks from re-infusion of the blood after processing by the machine such as infection or an adverse reaction to the blood components. However, this has not been seen in many thousands of volunteers who have undergone this or similar procedures to date. There may be other risks of apheresis that are unknown at this time.

During the leukapheresis procedure, your platelet count may decrease because platelets are collected with the white blood cells. Platelets are cells that help your blood to clot. Taking aspirin in combination with a lowered platelet count may increase your chance of developing bleeding. Therefore, you should not take aspirin or aspirin-containing drugs for 2 weeks after the procedure without physician approval.

Unknown Safety Risks

There may be side effects from the study vaccines - even serious or life-threatening ones- that we do not yet know about. Please tell the study staff about any side effect you think you are having. This is important for your safety.

Possible Risks from Stored Samples

We will collect blood samples from you during the study. We will keep these samples indefinitely for future research to learn more about flu virus, vaccines, the immune system, and other research questions. Results from research with your samples will not be in your medical record or reported to you.

Labeling of Stored Samples: Your stored samples will be labeled by a special code or number and not your personal information. Only the study team can link this code to you. Any identifying information about you (like name or date of birth) will be kept as confidential as allowable by law.

Risks of Stored Samples: There is a small chance that information from your medical records could be given to someone who should not get it without your permission. It is possible for someone to use that information to discriminate against you when you apply for insurance or employment. Similar problems may occur if you give information about yourself or agree to have your medical records released.

Possible Risks of Data Sharing

Information in the shared databases could be linked back to you and used to discriminate against you or your family. State and federal laws provide some protections against genetic and pre-existing conditions discrimination.

Possible Other Risks

We do not know if the study vaccine will change how your body responds to flu virus infections in the future.

You may not donate blood at a blood bank while taking part in this study. You may not donate blood for one year after the last experimental vaccine injection.

What are the Risks Related to Pregnancy?

We do not know how the experimental vaccines may affect a fetus or nursing infant. Therefore, women who can become pregnant must have a negative pregnancy test before the vaccine injection and agree to use effective birth control beginning at least 21 days before the injection until the end of the study. We will discuss effective methods of birth control with you.

Any time during the study you must tell the clinic staff right away if you become pregnant, your birth control method fails, or you think that you might be pregnant. If you are pregnant, you will be asked to continue with follow-up visits so that we can check your health. We will ask you the outcome of the pregnancy.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You will not benefit from being in this study.

Are there any potential benefits to others that might result from the study?

The study is not designed to protect you from flu. We do not know if the vaccine will work. You and others may benefit in the future from the information that will be learned from the study. The study visits are used to check your health for research purposes, not to provide health care. However, we will tell you right away if any of your test results show a possible health problem.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could choose not to take part. You may be eligible for other VRC studies.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

At each visit you will be checked for any health changes or problems. Blood will be drawn at almost every study visit to check on your health. You will be told right away, in person, by phone call, or by text message if any of your test results show a health problem.

The results of this study may be reported in medical journals, on the internet or at scientific meetings. We will give you information about how to find the study results once they are available.

EARLY WITHDRAWAL FROM THE STUDY

You may be removed from the research study by the researcher for any of the following reasons:

- You don't keep appointments or follow study procedures;
- You get a serious illness that needs ongoing medical care;
- You have a serious side effect thought to be due to the study vaccines;
- You become pregnant;
- You need to get treatment with a medication that affects your immune system (such as a steroid like prednisone);
- The study is stopped or cancelled;
- The researcher believes that it is in your best interest to remove you from the study;
- The study is stopped by regulatory agencies, the study sponsor, or study investigators. If this happens, we will tell you why.

If you agree to take part in this study, it is important for you to keep all of your appointments. Your participation in this study is completely voluntary. You can choose to stop taking part in the study at any time. There is no penalty or loss of benefits if you choose to leave the study. If you get the product administration during the study, we encourage you to take part in safety follow-up. It is important that we continue to check your health.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

Will your specimens or data be saved for use in other research studies?

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding influenza, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

If you agree to participate in this study, you give permission for your coded specimens and data to be stored and used for future research as described above.

Will your specimens or data be shared for use in other research studies?

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas that are similar to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

If you agree to participate in this study, you give permission for your coded specimens and data to be stored and used for future research as described above.

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future

research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. Usually, these researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

If you decide not to take part in this study, you may still take part in other studies at NIH.

How Long Will Your Specimens and Data be Stored by the NIH?

Your specimens and data may be stored by the NIH indefinitely.

Risks of Storage and Sharing of Specimens and Data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your specimens and data.

PAYMENT

Will you receive any type of payment for taking part in this study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will be compensated for your time and inconvenience by the NIH Clinical Research Volunteer Program. It is possible that you may have some expenses that are not covered by the compensation provided.

For all Groups the compensation is:

- $315 for the vaccination visit
- $25 total for the timely completion of all 7 days of an electronic diary
- $200 for each scheduled follow-up visit that includes a research blood draw
- $55 additional if a visit includes only a nose or throat swab
- $85 for all other clinic visits that do not include research blood draws or mucosal sample collection.
- $285 for optional apheresis

The total compensation for completion of all study visits is about $1,940 without apheresis and $2,025 with apheresis.

The total compensation you get is based on the number and type of study visits you complete. You will get the compensation about 2 weeks after each completed visit by direct deposit into a bank account that you specify to the Volunteer Payment Office.

If you are unable to finish the study, you will receive compensation only for the parts and visits you completed. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

The study team plans to collect social security numbers from research participants for purposes of compensation. Participants can withhold their social security numbers and still participate in the research study; however you may not be able to receive compensation if you do so.

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Revenue Service (IRS). A "Form 1099-Other Income" will be sent to you if your total payments for research participation are $600 or more in a calendar year. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

REIMBURSEMENT

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for parents and participants, or payment of, hotel, travel, or meals.

COSTS

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

There are no costs to you for participating in this study. You or your health insurance will have to pay for all medical costs for medical care that you get outside this study. It is possible that you may have some expenses that are not covered by the study compensation provided.

CONFLICT OF INTEREST (COI)

The NIH reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a COI Guide. You may ask your research team for a copy of the COI Guide or for more information. Members of the research team who do not work for NIH are expected to follow these

guidelines or the guidelines of their home institution, but they do not need to report their personal finances to the NIH.

The NIH and the research team for this study have developed the FluMos-v1 vaccine being tested in this study. This means it is possible that the results of this study could lead to payments to NIH. By law, the government is required to share such payments with the employee inventors. You will not receive any money from the development of the vaccine.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board
- The study Sponsor, VRC, or their agent(s)

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

- is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
- is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
- is for other research;
- is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator Alicia Widge, MD, MS; [redacted]. Other researchers you may call are: Floreliz Mendoza, RN; [redacted] You may also call the NIH Clinical Center Patient Representative at [redacted], or the NIH Office of IRB Operations at [redacted] if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date

Witness to the oral short-form consent process only:

Witness:

Signature of Witness*	Print Name of Witness	Date

***NIH ADMINISTRATIVE SECTION TO BE COMPLETED REGARDING THE USE OF AN INTERPRETER:**

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent and served as a witness. The investigator obtaining consent may not also serve as the witness.

____ An interpreter, or other individual, who speaks English and the participant's preferred language facilitated the administration of informed consent but did not serve as a witness. The name or ID code of the person providing interpretive support is: _____.